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NASTAD™
NATIONAL ALLIANCE OF STATE & TERRITORIAL AIDS DIRECTORS

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Bridging Science, Policy and Public Health

February 12, 2016

The Honorable Orrin G. Hatch
Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Grassley and Ranking Member Wyden:

On behalf of the National Alliance of State and Territorial AIDS Directors (NASTAD), the association that represents public health officials who administer HIV and hepatitis health care, prevention, education, and supportive service programs funded by state and federal governments, I am writing to commend the United States Senate Committee on Finance's recent report, *The Price of Sovaldi and Its Impact on the U.S. Health Care System*. NASTAD has long been concerned that rising drug prices negatively impact patient health, and the Committee's attention to this matter is critical in reversing this dangerous trend. Following the Committee's request, NASTAD has provided comments in response to the five questions outlined in the report.

1. What are the effects of a breakthrough, single source innovator drug on the marketplace?

The Committee's report has resoundingly demonstrated the negative impacts of the introduction of a breakthrough, single source innovator drug to the marketplace: increased costs for payers and patients, accompanied by burdensome access restrictions that impair patient health. As the Committee notes, if a competing product does not arrive on the market within a reasonable time, payer budgets and patient access are unduly burdened. Competition, however, can reduce these concerns. Congress should commission a study examining the impact of reduced patent exclusivity for products that are priced above the marginal value of the treatments to patients, as various value thresholds and tiered reductions in patent exclusivity could discourage manufacturers from establishing burdensome prices while maintaining a market-based system of pricing controls.

2. Do the payers in the programs have adequate information to know the cost, patient volume, and increases in efficacy of a new treatment regimen?

As the Committee's report concludes, payers did not have appropriate knowledge of the costs and treatment expectations of the new therapy, resulting in payers acting conservatively, implementing overly restrictive access barriers to prevent expected runaway costs. Because many patients may not be screened for chronic diseases that lack a treatment or cure, payers may reasonably be unaware of the potential patient demand for new treatment regimens. To encourage payers to avoid overly restrictive access barriers to new therapies, Congress should explore the development of re-insurance

programs that will support payers facing excessive costs based on unexpected demand for new breakthrough therapies. These programs must be coupled with provisions that encourage manufacturers to set appropriate prices for breakthrough therapies, rather than enabling manufacturers to set exorbitant prices through guaranteed payment.

3. What role does the concept of "value" play in this debate, and how should an innovative therapy's value be represented in its price?

NASTAD continues to applaud manufacturers for the development of Direct-Acting Antiretroviral (DAA) therapies that can cure, rather than simply treat, hepatitis C. NASTAD believes that Congress should encourage the development of further curative therapies for chronic conditions, including HIV, and that cures for these diseases have greater value than maintenance therapies. While the value of these therapies accrues over the long term via reductions in maintenance treatment costs and reduced side effects or subsequent hospitalizations, the costs accumulate immediately. NASTAD commends the Committee's efforts to expand value-based purchasing within Medicare Parts A and B, and NASTAD supports the Committee's call to introduce value-based purchasing into Medicare Part D. Congress should explore the feasibility of establishing reimbursement and re-insurance policies that would encourage appropriate payments for curative therapies, recognizing their long-term value. Because many insurance plans are subject to rate reviews and other restrictions that may not adequately account, ex ante, for patient demand for breakthrough therapies, Congress should consider re-insurance programs that will allow payers to extend broad access to breakthrough therapies with demonstrated value over present treatments. Congress should also call for additional study on whether rate review or other restrictions may discourage payers from investing in valuable curative therapies with long-term benefits because of present costs that are higher than maintenance therapies, as well as what changes to the rate review process could encourage a focus on long-term patient health and cost-savings.

4. What measures might improve price transparency for new higher-cost therapies while maintaining incentives for manufacturers to invest in new drug development?

Price transparency is a vexing issue in drug access, and NASTAD shares the Committee's concerns that lack of transparency impairs the development of a competitive drug market. However, in markets with few players, it is unclear that pricing transparency would dramatically lower prices, as the various players could use the publically available pricing to engage in tacit collusion to avoid lowering prices further, preventing individual payers from securing deeper discounts. Congress should commission research on the likely impacts of pricing transparency on eventual prices paid by both public and private payers, considering lessons learned in other markets with few producers and high barriers to entry (e.g., airlines).

As the Committee's report demonstrates, manufacturers base their drug prices on expectations of what the market will bear and the ability to maximize profits, not ensuring broad treatment access. Congress should explore the possibility of establishing a pricing review mechanism, similar to that used to evaluate insurance rates, to determine whether drug prices reflect the marginal costs of drug development rather than the maximum profit possible.

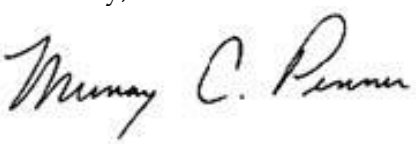
5. What tools exist, or should exist, to address the impact of high cost drugs and corresponding access restrictions, particularly on low-income populations and state Medicaid programs?

The impact of costly drugs and corresponding access restrictions uniquely burdens Medicaid programs and the low-income patients who depend on them. As they evaluate Medicaid funding, state lawmakers are poorly situated to assess upcoming cost increases for Medicaid following the approval of breakthrough therapies. Combined with requirements to balance state budgets and infrequent state legislative sessions, state lawmakers may not adequately fund Medicaid programs to cover forthcoming breakthrough therapies, even though early adoption of these therapies could result in significant long-term cost savings.

Congress should consider expanding Medicaid matching funds or providing mid-year supplemental funds to states to spur the rapid uptake of breakthrough therapies when early adoption would yield long-term cost savings, as the state may not be able to appropriate additional funds, even if it would generate cost-savings. The Centers for Medicare and Medicaid Services (CMS) could be provided authority to determine standards for designating cost-saving breakthrough therapies and establishing state access conditions that must be met before additional funding is provided to states. Similar to private re-insurance programs, these funds would prevent short-term cost considerations from hindering access to beneficial treatments that are cost-saving over the long-term. To avoid excessive costs, CMS and states should be able to use national buying power to negotiate additional discounts for Medicaid purchase of these drugs, contingent on states' adopting appropriate access programs as established by CMS.

NASTAD sincerely appreciates the opportunity to offer comments on the Committee's report. The Committee's attention to drug pricing and patient access is a timely response to a very pressing need. NASTAD believes that comprehensive drug pricing and access reform legislation is needed, and we are happy to assist the Committee in any future efforts.

Sincerely,



Murray C. Penner
Executive Director